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EXAMINER	
HIBBERT, CATHERINE S	
ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,169	BURCZYNSKI ET AL.	
	Examiner	Art Unit	
	Catherine S. Hibbert	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,7,9-11 and 17-27* is/are pending in the application.

4a) Of the above claim(s) *6 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7,9-11,17 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/15/2005,9/15/2005,7/5/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Please note that the examiner of this application has changed. Applicants' Amendments to the Claims filed 5 July 2007 have been received and entered. Applicants' Information Disclosure Statement filed 5 July 2007 have been received and entered. Claims 2-3, 5, 8, and 12-16 are cancelled. Claims 1, 4, 6-7, 9-11, 17-27 are pending. Claims 6 and 18-20 are withdrawn. Claims 21-27 are new. Claims 1, 4, 7, 9-11, 17 and 21-27 are under examination in this Office Action.

Response to Arguments

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: It does not identify the citizenship of each inventor.

Applicants have requested that this objection be held in abeyance until Applicants submit a supplemental declaration when all the inventors have signed the supplemental declaration. Applicants request for an abeyance is acknowledged.

The objections to claims 4 and 9 have been withdrawn based on Applicant's Amendment to the Claims, filed 5 July 2007.

The rejection of claims 1, 4, 7, and 9-10 under ¶ 112(second paragraph), has been withdrawn based on Applicant's Amendments to the Claims. The rejection of cancelled claims 2-3, 5, 8, 12, and 14-16 is moot.

The rejection under 35 USC ¶ 102(b), has been overcome based on Applicant's Amendments to the Claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 7, 9-11, 17 stand rejected and new claims 21-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record and for reasons below. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection of cancelled claims 2-3, 5, 8, 12, and 14-16 is moot.

Applicants' arguments have been fully considered but they are not persuasive.

Applicants traverse the rejection on the grounds that the amended claim 1 recites a method for detecting *in vivo* CCI-779 activity in a patient having a solid tumor by generating an expression profile of at least one CCI-779 activity gene selected from Table 5 in a peripheral blood sample obtained from the patient having the solid tumor

and at a stage of treatment with CCI-779 and comparing the expression profile to a reference expression profile, wherein a statistically significant change in the expression profile of said at least one CCI-779 activity gene compared to the reference expression profile is indicative of the *in vivo* CCI-779 activity. In other words, Applicants state that "amended claim 1 recites a method for simply detecting the presence of *in vivo* CCI-779 activity based on the expression profile of specific CCI-779 activity genes selected from Table 5, *i.e.*, genes specifically modulated by *in vivo* CCI-779 activity".

Furthermore, Applicants argue that contrary to the Office Action's allegation, amended claim 1 does not require using any "drug activity gene" as a biomarker or surrogate endpoint for efficacy in the treatment of any non-blood disease with any drug therapy. Applicants recite "Amended claim 1 also does not require determining disease state or efficacy of drug therapy, as discussed in Wagner, Frank, Feng or Twine relied on by the Office Action". Therefore, Applicants submit that the unpredictability as to the use of biomarkers to determine disease state and efficacy of drug therapy does not apply to amended claim 1.

> Therefore, Applicants submit that the present specification fully enables one of skill in the art to practice the method as claimed in claim 1 for the following reasons: First, the CCI-779 activity genes recited in claim 1 are genes that are specifically modulated by *in vivo* CCI-779 activity identified by the present invention. The names and sequences of such CCI-779 activity genes are provided in Table 5. Therefore, one of ordinary skill in the art, upon reviewing the specification, would readily have understood which CCI-779 activity gene to look at. Secondly, the present specification provides sufficient guidelines on how to generate an expression profile of at least one CCI-779 activity gene selected from Table 5 in a peripheral blood sample obtained from the patient having the solid tumor and at a stage of treatment with CCI-779. For example, methods for generating expression profiles are described at least in paragraphs 0022-0027, 0422-0453 and Examples 1 and 2. Methods for obtaining peripheral blood samples from the patient at different stages of treatment of CCI-779 are

> described at least in paragraphs 0028 and 0029. Thirdly, the present specification provides sufficient guidelines on how to compare the expression profile of the at least one CCI-779 activity gene to a reference expression profile and to detect a statistically significant change in the expression profile based on the comparison result.

As an example, Applicants point out the methods for comparing the expression profile of a sample of interest to a reference expression profile are described in paragraphs 0454-0460 and Example 3. In addition, Applicants state that methods for detecting statistically significant difference between the expression profile and the reference expression profile are provided in paragraphs 0458 and 0467-0467. Therefore, Applicants submit "that one of ordinary skill, upon reviewing the specification, would readily have been able to carry out the method as claimed in claim 1 without undue experimentation".

Applicants further traverse the enablement rejection by stating that the "amended claim 17 recites a method for identifying genes modulated by CCI-779 by generating an expression profile of a peripheral blood sample obtained from a patient having a solid tumor and at a stage of treatment with CCI-779 and comparing the expression profile to a reference expression profile to identify one or more differentially expressed genes". Furthermore, Applicants argue that "contrary to the Office Action's allegation, amended claim 17 does not require using any "drug activity gene" as a biomarker or surrogate endpoint for efficacy in the treatment of any non-blood disease with any drug therapy". Applicants further point out that the Amended claim 17 also "does not require determining disease state or efficacy of drug therapy, as discussed in Wagner, Frank, Feng or Twine relied on by the Office Action". Therefore, Applicants submit that the

unpredictability as to the use of biomarkers to determine disease state and efficacy of drug therapy does not apply to amended claim 17.

Applicants further submit that the present specification fully enables one of skill in the art to practice the method as claimed in claim 17 for the following reasons:

> First, the present specification provides sufficient guidelines on how to generate an expression profile in a peripheral blood sample obtained from a patient having a solid tumor and at a stage of treatment with CCI-779 and to compare it to a reference expression profile to identify one or more differentially expressed genes. For example, methods for generating expression profiles are described at least in paragraphs 0022-0027, 0422-0453 and Examples 1 and 2. Different stages of CCI-779 treatment are described in paragraphs 0029 and 0039. Methods for comparing the expression profile of a sample of interest to a reference expression profile are described in paragraphs 0454-0460 and Example 3. Guidelines on how to detect differentially expressed genes are provided in paragraphs 0458 and 0467-0467. Furthermore, the present specification provides numerous working examples of genes modulated by CCI-779 identified by the method as claimed in claim 17. For example, exemplary genes modulated by CCI-779 are shown in Tables 2-6.

Therefore, Applicants submit that one of ordinary skill, upon reviewing the specification, would readily have been able to carry out the method as claimed in claim 17 without undue experimentation.

Applicants' arguments have been fully considered but are not persuasive because enablement is considered in view of the Wands factors (MPEP 2164.01(A)) . These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art, the amount of experimentation necessary and the relative skill levels of those in the art. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention and Breadth of the Claims: The claims are drawn to methods comprising a comparison between an expression profile from at least one "CCI-779 activity gene" (selected from among the 310 genes listed in Table 5) in a peripheral blood sample of a patient having a solid tumor and "at a stage of treatment with CCI-779" to a "reference expression profile". While claim 21 is drawn to such a method comprising the use of profilin-I, the rest of the claims encompass the use of any gene or set of genes from selected from among the 310 genes listed in Table 5. While claim 4 is drawn to such a method wherein the patient has a renal cell carcinoma (RCC), the rest of the claims encompass any patient having a solid tumor. The nature of the invention is complex in that gene expression patterns involving potentially thousands of different genes are involved. Furthermore, the PBMCs from which the expression patterns will be obtained are not themselves diseased and are only presumed to comprise genes which can be modulated by the CCI-779 in a way that is indicative of a "CCI-779 activity gene." In addition, the invention reads on *any* reference peripheral blood sample from said patient, including, for example, a patient who has received CCI-779 treatment just hours before the "stage of treatment with CCI-779" to which the reference sample results are being compared. Thus, the invention is broad in scope and very complex.

Guidance Provided by the Specification .and the Existence of Working Examples: The specification teaches that the invention employs PBMCs "as surrogate tissues for the detection of in vivo activities of CCI-779 or other drugs" (see pages I-2, paragraph [0004]). The specification further teaches that the invention employs systematic gene

expression analysis to identify genes whose expression in peripheral blood can be modulated by a therapeutic agent such as CCI-779 (see page 5, paragraph [0019]). These "drug activity genes" can further be utilized such that changes in the peripheral blood expression profile of such genes are indicative of the in vivo activity of the drug therapy (page 4, [0017]). The specification discloses 310 CCI-779 activity genes in Table 5, so identified (see page 39-45, Table 5, paragraph [0041]). In addition, Applicants present no guidance on the practicing of the claimed invention with regards to reference samples *taken after* a CCI-779 exposure. In addition, Applicants present no working examples of the claimed invention with regards to reference samples *taken after* a CCI-779 exposure.

On the whole, the disclosure appears to assert that, because differences in gene expression can be determined among genes expressed in PBMCs from a subject with a non-blood disease pre- and post-drug therapy, and because these genes can be identified, differences in PBMC gene expression before and after drug treatment would be indicative of the in vivo effect of a drug therapy upon any given non-blood disease. However, the specification does not provide a single working example of such a complex method, wherein the genes identified before and at different stages of CCI-779 treatment are indicative of the in vivo activity of the drug therapy utilized, especially with regard to the effect of the drug therapy upon the solid tumor. Nor does the specification teach how a difference in one gene's expression (be it profilin-1 or any other gene selected from Table 5) should or could be measured such that the difference is indicative of CCI-779's activity on the solid tumor.

State of the prior art and level of predictability in the art: The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. The physiological art is recognized as unpredictable (MPEP 2164.03). As set forth in In re Fischer, 166 USPQ 18 (CCPA 1970), compliance with 35 USC §112, first paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resorting to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The question of predictability in the instant case has to do with whether the skilled artisan would be able to extrapolate from the disclosed CCI-779-modulated genes and the knowledge available in the art regarding the correlated effects of drug therapy upon any solid tumor (or RCC/claim 4) and the simultaneous changes in PBMC

gene expression, such that the skilled artisan could practice the claimed method to determine if changes in the PBMC expression profiles before and and/or at different stages of drug treatment were indicative of the in vivo activity of the drug on the solid tumor.

The claimed method proposes to use any "drug activity gene" selected from Table 5 (or profilin/ claim 21) as a biomarker or surrogate endpoint for efficacy in the treatment of any solid tumor (or RCC/claim 4) with CCI-779 drug therapy. The art recognizes that before a putative biomarker can be used as a surrogate endpoint it must be validated as such. Wagner (Dis. Markers 18(2):41-46, 2002, made of record in the Office Action mailed 4 April 2007) acknowledges in the Abstract, "Putative biomarkers are typically identified because of a relationship to known or hypothetical steps in a pathophysiologic cascade. Biomarker discovery can also be effected by expression profiling experiment using a variety of array technologies and related methods." However, Wagner cautions, "A rational basis for recommending the use of a putative biomarker does not guarantee the utility of the biomarker or its qualification as a surrogate endpoint" (paragraph bridging the left and right columns on page 43) and "Biomarkers require validation in most circumstances" (paragraph bridging pages 43-44). Frank et al. (Nature Rev. 2:566-580, 2003, made of record in the Office Action mailed 4 April 2007) concurs, stating, "The standard concepts of test-re-test reliability and validity apply with equal force to clinical biomarkers as they do in any assay system" and, "The work required to establish the reliability and validity of a new biomarker should not be underestimated in general, and in particular needs of planning

for each combination of clinical indication and mechanism of action" (paragraph bridging the left and right columns on page 568). Feng et al. (Pharmacogenomics 5:709-719, 2004, made of record in the Office Action mailed 4 April 2007) teaches, "The development and validation of clinically useful biomarkers from high-dimensional genomic and proteomic information pose great research challenges. Present bottle necks include: that few of the biomarkers showing promise in initial discovery were found to warrant subsequent validation. A molecular profiling approach, although promising, has a high chance of yielding biased results and overfitted models" (Abstract).

Viewed as a whole, the art clearly teaches that the utility of a putative biomarker as a surrogate endpoint for any disease state is unpredictable and must be validated. With regard to the use of biomarkers in renal cell carcinoma (RCC), an article published after Applicant's effective filing date describes "disease-associated" expression profiles in peripheral blood mononuclear cells (PBMCs) from patients with advanced renal cell carcinoma (Twine et al. Cancer Research 63(18) :6069-6075, 2003, made of record in the Office Action mailed 4 April 2007). However, Twine et al do not disclose that such gene expression patterns can be used to detect RCC in a patient. Rather, Twine et al teach the presence of expressed, disease-associated genes in the PBMCs of RCC patients, which if additional experiments were to bear such findings out, could "represent the foundation on which to build disease-specific gene sets that can be used as part of a molecular diagnosis of disease using peripheral blood" (see page 6075, last paragraph, as well as page 6074, Figure 2). Twine et al. also teach that "it is currently

unknown whether in the context of RCC or any other active solid tumor burden there exists correspondingly distinct markers of gene expression in the PBMCs of affected individuals" (page 6069, first column, first paragraph). Thus, even after Applicant's effective filing date the art does not recognize gene expression profiles from PBMCs which are necessarily diagnostic of renal cell carcinoma. It would therefore be an even larger hurdle to determine from among those putative biomarkers of RCC, those genes which could act as surrogates for the efficacy of a drug therapy upon RCC.

Thus, the state of the prior art with regard to the use of surrogate endpoints in general was underdeveloped and unpredictable at the time of Applicant's filing; the state of the art was silent with regard to the use of PBMC biomarkers to determine the efficacy of drug therapy on RCC in particular.

Amount of Experimentation Necessary: Given the underdeveloped state of the art and the level of unpredictability in the art, One of ordinary skill in the art would have been required to perform an undue amount of experimentation in order to first, accurately determine gene expression differences in PBMCs of patients with a solid tumor before and/or after different stages of drug treatment. Then, once differences in gene expression were found (if any), one of ordinary skill in the art would have to determine which of those difference were indeed indicative of the drug therapy and could therefore be used as an indication of the drug's activity in vivo. The in vivo drug activity on PBMC gene expression and upon the solid tumor would need to be correlated. This amount of experimentation is exacerbated by the breadth of the claims, which would require one of ordinary skill in the art to determine which genes from Table

5 (or profilin) were associated before and/or at different stages after treatment with CCI-779 for any solid tumor (or RCC).

"It must be remembered...that ' [p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Genentech, 108 F.3d at 1366 (quoting Brenner v. Manson, 383 U.S. 519, 536 [148 USPQ 689] (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion')). Thus, while the need for some experimentation is by no means necessarily fatal, 'reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.' Id." University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 at 1436 (W.D.N.Y. 2003).

Given no more than what is provided in the instant application and the relevant art, the skilled artisan would not know how to practice the claimed invention (i.e., which differences in gene expression to use in combination with which solid tumors such that the difference(s) in gene expression were indicative of the drug therapy's efficacy in vivo. Given the unpredictable nature of the invention and the broad scope of the claims, the amount of experimentation would clearly be undue. Therefore, the disclosure fails to adequately enable the claims and the claims are properly rejected under 35 U.S.C. §112, first paragraph.

Claims 1, 4, 7, 9-11, and 17 stand rejected and new claims 21-27 (added by Applicants' Amendment) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record and for reasons above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4 and 10-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/793,032. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons of record as stated in the office action mailed 4 April 2007. The rejection of cancelled claims 2-3 is moot.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response Applicants request that the provisional nonstatutory obviousness-type double patenting rejection be held in abeyance until such time that the presence of otherwise-allowable subject matter is acknowledged. At such time, Applicants state that they intend to file an appropriate terminal disclaimer over the co-pending application, U.S. Serial No. 10/793,032.

Applicant's statement, filed 5 July 2007, regarding the Double Patenting rejection is acknowledged.

Claims 1, 4 and 10-11 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting for reasons of record as stated in the office action mailed 4 April 2007 and above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert whose telephone number is 571-270-3053. The examiner can normally be reached on Monday-Friday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully submitted,

Catherine S. Hibbert/AU1636

DAVID GUZO
PRIMARY EXAMINER